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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,714	02/25/2002	Robert W. Henkens	4320-0018DIV.	5829

7590 03/21/2006

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EXAMINER	
RILEY, JEZIA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,714	HENKENS ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

1. Applicants' arguments, filed on 1/30/06, have been approved and entered. They have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Wohlstadter et al. (Pub. No.: US 2004/00864233 A1).

Wohlstadter et al. discloses materials and methods for producing patterned multi-array, multi-specific surfaces (PMAMS) for use in diagnostics. Wohlstadter provides for electrochemiluminescence methods for detecting or measuring an analyte of interest; novel electrodes for ECL assays; materials and methods for the chemical and/or

physical control of conducting domains and reagent deposition for use multiply specific testing procedures.

The reference relates to a cassette for conducting ECL reactions and assays comprising one or more binding domains immobilized on a support. The support may act as an electrode for generating electrochemiluminescence. The binding domains are patterned on a support surface and are prepared so as to bind analytes or reagents of interest. ECL assay methods are disclosed for detecting or measuring an analyte of interest, comprising (a) contacting one or more binding domains immobilized on an electrode, in which said contacting is with a sample comprising molecules leveled to an ECL label, (b) applying a voltage waveform effective to trigger ECL at said binding domains, and (c) measuring or detecting ECL. (Pages 2, 6-7, 14).

Oligonucleotides bound to an electrode surface can be utilized as a binding agent in a binding domain. (page 21).

A series of voltage waveforms is applied so as to generate a multiplicity of ECL signals. Further, multiple electronic potential waveform pulses may be utilized to reduce undesirable modulation of signal due to non-specific binding. Electronic potential may be applied to prevent non-specific binding of certain charged species. Additionally, electronic potential may be applied so as to promote the localization near a binding domain(s) of certain analytes or chemical species of interest. The voltage waveform applied supplies large over-potential (e.g., higher potential than is required to generate

ECL). Over-potentials may be utilized to modulate ECL signals in a voltage wave series or in a single voltage wave pulse. (page 22).

Measurements of ECL at different binding domains can be done sequentially or simultaneously. (page 27).

The formation of PMAMS on the surface of a composite electrode can be achieved by a variety of methods including photolithographic immobilization, microcontact printing and/or the controlled application of drops of binding reagents to the surface through the use of microcapillary arrays or ink-jet printing. (page 27).

A support having a PMAMS may be used for sequencing of nucleic acid strands. For example, a PMAMS with a plurality of binding domains is prepared with different oligonucleotide probes of known nucleotide sequence as the binding reagents in different binding domains. That is, different binding domains will contain binding reagents of different known nucleotide sequence. The oligonucleotide chain or fragments of the oligonucleotide chain to be sequenced are then allowed to bind (hybridize) to the PMAMS binding domains. The nucleic acids to be sequenced are ECL labeled. Binding assays are conducted on the PMAMS and the distribution of ECL signals from the discrete binding domains on the PMAMS is used to sequence the oligonucleotide chain.(page 27).

4. Response to Arguments:

Applicants argue that Wohlstadter et al do not teach or disclose the instant biosensor because Wohlstadter et al. do not teach altering the potential of an electrode

to detect target nucleic acid specifically and selectively by current produced at the electrode. And as opposed to Wohlstadter, the instant application measure the current produced by the capture of target nucleic acid; that is the current is target induced and not applied by the apparatus; that the current is produced by the hybridized electrode bound nucleic acid target sequences when an electrical potential is applied. And that the instant apparatus that is a small, portable instrument that applies potential to a working electrode is the same instrument that transfers records analyses and /or displays the current generated by the electrochemical assays. Further applicant argue that Wohlstadter do not establish an appropriate potential so current can be generated at the electrode and used for nucleic acid detection, etc...

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-11, 13, 14, and16 are rejected under 35 U.S.C. 102(e) as being anticipated by Doung et al. (US 2002/0177135A1).

Doung et al. discloses devices configured to hold multiple cartridges comprising biochips. Said biochips comprise a substrate with at least one surface comprising an array of electrodes, (page 7, paragraph 0067). The devices comprise a number of cartridge stations that are configured to receive the biochips, with different types of biochips allowing different types of components. The stations can include a wide variety of different components, including thermocontrollers, signaling systems, sensors for leak detection, alphanumeric displays, and detectors. Preferred embodiments include the use of biochips comprising electrodes that rely on electrochemical detection, and thus the devices and/or stations can comprise device boards and processors. (Paragraph 0030 and 0065). As will be appreciated by those in the art, the cartridge can comprise a number of components, including reaction chambers, inlet and outlet ports, heating elements including thermoelectric components, RF antennae, electromagnetic components, memory chips, sealing components such as gaskets, electronic components including interconnects, multiplexers, processors, etc. (paragraph 0050). Doung et al. provide methods and compositions for the multiplex analysis of samples and target analytes. Samples (either raw samples or treated samples (e.g. amplified, purified, etc.)) are loaded into the cartridges of the invention, optional caps are put on, and the cartridges loaded into a station of the device.

Additional reagents are added as necessary, and assay complexes formed. (Paragraph 0358). Which is viewed to be inclusive of instant claims 13 and 16.

Structure 17 on page 20 shows that said electrodes comprise nucleic acids covalently attached. Said electrodes are used in hybridization assay using ETM labels. And said ETM can be detected electronically by monitoring electron transfer. (see pages 25, 31, 32, 35, 41). And said monitoring can be done via amperometric detection (page 36). This method of detection involves applying a potential. Electron transfer of differing efficiencies is induced in samples in the presence or absence of target nucleic acid; that is the presence or absence of the target nucleic acid and thus the label probe, can result in different currents (paragraph 0371, pages 36-37). Electrodes can be made that have a single species of nucleic acid or multiple nucleic acid species (paragraph 0424). Said devices are also used for quantification (paragraph 0426).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doung et al. (US 2002/0177135A1) in view of Stratagene catalog 1988 page 39.

Goung et al. is recited above.

Stratagene shows gene characterization kits providing a variety of different reagents. Each kit provides a variety of different reagents, which have been assembled and premixed specifically for a defined set of experiments.

Thus, it would have been obvious to someone of ordinary skill in the art, at the time the invention was made to prepare a kit comprising the biosensor as shown by Doung et al to determine the presence of a nucleic acid target in a sample and using appropriate reagents as showed by Stratagene.. One would have been motivated to perform this kit as suggested by Stratagene, because it saves money and resources by reducing waste reagents since each of these reagents is needed in only microgram amounts when beginning a series of experiments, thus reducing the accumulation of unused chemicals (see lines 12-27 Stratagene catalog p.39).

9. Response to Arguments:

Applicants argue that Doung et al. does not teach or suggest the instant application because a biosensor array need not contain a self assembled monolayer or an inlet port for the introduction of reagents. The claims are directed to a method "comprising" therefore they can include other steps or means. Additionally applicants state that Doung et al. does not teach or disclose method by which biosensor arrays can be used to detect nucleic acid. However the instant invention is not claiming a biosensor array but a circuit board biosensor apparatus. Therefore it is unclear why exactly the applicants are arguing. But as stated in the previous office action, Doung et al. discloses devices configured to hold multiple cartridges comprising biochips. Said biochips comprise a substrate with at least one surface comprising an array of electrodes. Structure 17 on page 20 shows that said electrodes comprise nucleic acids covalently attached. Said electrodes are used in hybridization assay. Further applicants state that Doung et al. does not teach or disclose how to avoid cross-talk between electrodes, how to deal with variation, and does not show how to quantify the data. The applicants also state that they describe the use of biosensor arrays for enzyme-enhanced amperometric detection of nucleic acid. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also states that Doung et al. does not teach that the current is target induced. This is not convincing because Doung et al. discloses: This method of detection involves applying a potential. Electron transfer of differing efficiencies is induced in samples in the presence or absence of target nucleic acid; that is the presence or absence of the target nucleic acid and thus the label probe, can result in different currents (paragraph 0371, pages 36-37).

10. After reviewing the parent case 10/044, 204 and the provisional application 60/040949, it has been concluded that the instant claims only have priority to parent 09/549,853 filed 4/14/2000. The limitations "a plurality of working and reference electrodes" and "a plurality of nucleic acid segments attached to the plurality of working electrodes" can not be found in applications 10/044, 204 and 60/040949. A declaration under 37 C.F.R. §1.131 can be filed to overcome the rejection.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then

the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, March 16, 2006

JEZIA RILEY
PRIMARY EXAMINER